

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

Induction Therapies, LLC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 8:21-cv-00604
)	
Ingenes, LLC. and)	
Dr. Krishnamurthy Govindaraj)	
)	
Defendants.)	

ANSWER AND COUNTERCLAIM OF DEFENDANT INGENES

Defendant/Counter-Plaintiff Ingenes, LLC (“Defendant” or “Ingenes”) and Defendant Krishnamurthy Govindaraj (“Govindaraj”) by and through its undersigned counsel, hereby answers the Complaint of Plaintiff/Counter-Defendant Induction Therapies, LLC (“Plaintiff” or IT”) in the above-captioned action and states as follows:

1. The Plaintiff is a company organized under the laws of South Dakota, registered with the Kentucky Secretary of State, with its principal office located at 1920 Stanley Gault Parkway, Suite 100, Louisville, Kentucky 40223.

RESPONSE: Defendant lacks sufficient information to form a belief as to the truth of the allegations of Paragraph 6 of the Complaint and therefore the allegations are denied.

2. The Defendant Ingenes is a company organized under the laws of Delaware. To the best of Plaintiff's knowledge and belief, its principal office is located at 16192 Coastal Highway, Lewes, DE 19958. Defendant's agent for service of process in is Harvard Business Services, Inc., also located at 16192 Coastal Highway, Lewes, DE 19958.

RESPONSE: Defendants admits Ingenes LLC it is Delaware limited liability company.

Defendants denies Ingenes principal office is in Lewes, Delaware. Defendants admits Ingenes agent for service of process in is Harvard Business Services, Inc., also located at 16192 Coastal Highway, Lewes, DE 19958.

Defendant Govindaraj admits he is the sole member of Ingenes, LLC, and resides at 10135 Treble Court, Rockville, MD 20850.

3. Jurisdiction is proper pursuant to Kentucky Revised Statute 454.210 ("KRS 454.210).

RESPONSE: Paragraph 4 contains legal conclusions as to which no response is required. Defendants further state that since this action has been removed, the jurisdiction and venue allegations are no longer applicable.

4. The damages sought in this action exceed the jurisdictional threshold of this Court.

RESPONSE: Paragraph 4 contains legal conclusions as to which no response is required. Defendant further states that since this action has been removed, the jurisdiction and venue allegations are no longer applicable. Notwithstanding the foregoing Defendants admit that there is diversity jurisdiction in this case.

5. On or about December 26, 2018 the Plaintiff and Defendant Ingenes entered into a consulting agreement, pursuant to which Defendant Ingenes was to work with Plaintiff to prepare and submit a 510k application with the Food & Drug Administration ("FDA") for a product manufactured by Plaintiff..

RESPONSE: Defendant admits Ingenes entered into a consulting agreement with relating services related to a 510(k) FDA submission. Defendant refers the Court to the Agreement referenced in the Complaint for its full content, meaning and legal import, if any. To the extent the allegations in Paragraph 5 of the Complaint are inconsistent with the agreement, or do not contain legal conclusions to which no response is required, the allegations are denied.

6. Defendant Govindaraj is an alter ego of Defendant Ingenes. That at all times relevant to this litigation, Plaintiff dealt directly with Defendant Govindaraj, relied on the advice and consulting services of Defendant Govindaraj, and had no dealings with any other individual claiming to be an employee or agent of Defendant Ingenes.

RESPONSE: The allegation that Govindaraj is an alter ego of Ingenes is a conclusion of law and no response is required. To the extent a response is required, the allegation is denied. With respect to the remainder of the allegations in Paragraph 6 of the Complaint, Defendants admits Govindaraj dealt with Plaintiff. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations of Paragraph 6 of the Complaint and therefore the allegations are denied.

7. That the pricing for services in connection with this submission were clearly set forth in the agreement. That Defendants were acting as Plaintiff's agents while contracting for testing and other services necessary to complete Defendants' duties pursuant to the agreement.

RESPONSE: Defendant refers the Court to the Agreement referenced in the Complaint for its full content, meaning and legal import, if any. To the extent the allegations in Paragraph 5 of the Complaint are inconsistent with the agreement, or do not contain legal conclusions to which no response is required, the allegations are denied. Defendant Ingenes admits that it acted as Plaintiff's consultant in connection with its obligations under the Agreement. Any other allegation in Paragraph 7 is denied.

8. That the Plaintiff believes that it has been overcharged for services covered by the Agreement and has therefore requested multiple times over a period of months, documentation in support of the charges from both Defendants, and Defendants refuse to provide Plaintiff with any invoices, receipts, or other proof of charges made and billed to Plaintiff.

RESPONSE: Defendants lack sufficient information to form a belief as to the truth of the allegations of Paragraph 6 of the Complaint that relate to Plaintiff beliefs and therefore the allegations

are denied. The remainder of the allegations in Paragraph 8 are also denied. Defendant Govindaraj specifically denies he has any obligations under the Agreement.

9. That, on or about December 31, 2019, Defendants filed some documentation with the FDA, but that documentation did not constitute a complete 510k submission as set forth in the agreement. That, to date, Defendants have failed to complete and file the 510k submission per the agreement.

RESPONSE: Defendant admits Ingenes filed an incomplete 501(K) submission at Plaintiff's request. Defendant refers the Court to the Agreement referenced in the Complaint for its full content, meaning and legal import, if any. To the extent the allegations in Paragraph 9 of the Complaint are inconsistent with the agreement, or do not contain legal conclusions to which no response is required, the allegations are denied. Defendant Ingenes specifically denies it failed to perform under the Agreement. Defendant Govindaraj denies he has any obligations under the agreement

**COUNT 1: BREACH OF CONTRACT (as
to both Defendants)**

10. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

RESPONSE: Defendants reasserts its responses to Paragraphs 1-10 hereinabove

11. Plaintiff and Defendants entered into a contractual agreement on or about December 16th, 2018.

RESPONSE: Defendants admit that Ingenes entered into an agreement with Plaintiff on or about December 16, 2018. Any other allegation in Paragraph 11 is denied.

12. Defendants had a duty to perform and complete their contractual obligations to Plaintiff under the contract. Defendants have refused on multiple occasions to cooperate with Plaintiff or to respond to Plaintiff's requests for information in connection with the agreement. To date, the 510k submission, which was the subject of the agreement, has not been fully completed or submitted to the FDA.

RESPONSE: Defendants admit that Ingenes had contractual obligations to Plaintiff that are set forth in the Agreement. Defendant refers the Court to the Agreement referenced in the Complaint for its full content, meaning and legal import, if any. Defendant Ingenes admits that it has refused to provide continuing support to Plaintiff after Plaintiff has refused to pay for services rendered by Ingenes outside the scope of the Agreement and agreed to by Plaintiff. Defendants lack sufficient information to admit or deny whether a 510k submission has been completed or submitted to the FDA.

13 That Plaintiff has paid approximately \$423,929.60 to Defendants in connection with the 510k submission. That Plaintiff has requested supporting documentation for all charges made to Plaintiff by Defendants in connection with their work under the agreement, and that Defendants refuse to provide this information.

RESPONSE: Defendants admit that Plaintiff has made partial payments to Ingenes under the Agreement and for services performed that were not contemplated under the Agreement. Defendants denies the remainder of the allegations in Paragraph 13.

14. That Plaintiff has requested from Defendants copies of all documentation contained in Plaintiff's file held by Defendants, as well as a copy of what Defendants submitted to the FDA on or about December 31, 2019 on behalf of Plaintiff, which is Plaintiff's intellectual property. Defendants refuse to produce this Documentation.

RESPONSE: Defendants admits it Plaintiff has requested copies of documents and Defendant has refused to prove them. Defendants denies that such materials comprise "Plaintiff's intellectual property." Any remaining allegation in Paragraph 14 of the complaint is also denied.

15. Defendants' failure to provide supporting documentation for charges which have been made to and paid by Plaintiff to Defendants, failure to produce copies of Plaintiff's file, and failure to complete and file the 510k submission to the FDA are material breaches of the agreement, and such breaches were the actual and proximate cause of harm to Plaintiff.

RESPONSE: Defendants deny the allegations of Paragraph 15 of the Complaint.

16. Accordingly, Defendants are liable in damages to Plaintiff in excess of \$100,000.00, the exact amount to be proven at trial, arising out of Defendants' breach of the parties' agreement.

RESPONSE: Paragraph 16 of the Complaint is a demand for damages and no response is required. To the extent that response may be required, Defendants deny that they are liable for any damages.

BREACH OF FIDUCIARY DUTY

17. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

RESPONSE: Defendant reasserts its responses to Paragraphs 1-17 hereinabove

18. At all times relevant to this litigation, Defendants were acting as agents for Plaintiff, and owed Plaintiff a fiduciary duty.

RESPONSE: Denied.

19. That Defendants intentionally breached this duty on more than one occasion, and such breaches were the actual and proximate cause of harm to Plaintiff.

RESPONSE : Denied.

20. Accordingly, Defendants are liable in damages to Plaintiff in excess of \$100,000.00, the exact amount to be proven at trial, arising out of Defendants' breach of their fiduciary duty to the Plaintiff.

RESPONSE: Denied.

21. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

RESPONSE: Defendant reasserts its responses to Paragraphs 1-22 hereinabove

22. At all times relevant to this litigation, Defendants had a duty not to convert Plaintiff's

property to Defendants' own use and benefit.

RESPONSE: The allegation is an assertion of law, and no response is required. To the extent a response is required, Defendants deny the allegations.

23. Defendants have breached that duty on more than one occasion, and such breaches were the actual and proximate cause of harm to Plaintiff.

RESPONSE: Denied.

24. Accordingly, Defendants are liable in damages to Plaintiff in excess of \$100,000.00, the exact amount to be proven at trial, arising out of Defendants' breach of their fiduciary duty to the Plaintiff.

RESPONSE: The allegations in paragraph 30 are a demand for relief and no response is required. Defendant denies that Plaintiff is entitled to any relief.

COUNT IV: TEMPORARY AND PERMANENT INJUNCTIVE RELIEF (as to both Defendants)

25. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

RESPONSE Defendant reasserts its responses to paragraphs 1-25 hereinabove

26. Plaintiffs have been, and continue to be, irreparably harmed by Defendants' actions and inactions.

RESPONSE: The allegations in paragraph 26 of the complaint are denied.

27. Monetary damages would be insufficient to fully compensate Plaintiff for such harm.

RESPONSE: The allegations in paragraph 27 of the complaint are Denied.

28. Plaintiffs have shown a substantial likelihood of success on the merits.

RESPONSE: The allegations in paragraph 28 of the complaint are Denied.

29. The equities weigh in favor of injunctive relief.

RESPONSE: The allegations in paragraph 29 of the complaint are denied.

30. Temporary and permanent injunctions would be in the public interest.

RESPONSE: The allegations in paragraph 30 of the complaint are Denied.

31. Plaintiffs therefore request a temporary and permanent injunction requiring Defendants to produce to Plaintiff all of Plaintiff's property now being wrongfully withheld by Defendants.

RESPONSE: The allegations in aragraph 31 are a demand for relief and no response is required. Defendant denies that Plaintiff is entitled to any relief.

COUNT V: COURT COSTS AND ATTORNEY'S FEES

(as to both Defendant's)

32. Plaintiff restates and incorporates by reference all previous paragraphs as if fully stated herein.

RESPONSE: Defendants reasserts its responses to paragraphs 1-32 hereinabove

33. Plaintiff respectfully request a reasonable award of its court costs and attorney's fees, whether pursuant to contract, equity, statute or common law.

RESPONSE: The allegations in paragraph 33 are a demand for relief and no response is required. Defendants denies that Plaintiff is entitled to any relief.

AFFIRMATIVE DEFENSES

As and For A First Affirmative Defense

(Failure to Assert a Claim)

1. Plaintiff's claims are barred in whole or in part because they fail to state a claim upon which relief may be granted.

As and For A Second Affirmative Defense

(Anticipatory Breaches, Breaches)

2. Plaintiff's claims are barred in whole or in part due to Plaintiffs' anticipatory breaches and breaches of the aforementioned agreements.

As and For A Third Affirmative Defense

(Failure of Condition Precedent)

3. Plaintiff's claims are barred in whole or in part because, to the extent that there was any breach of contract, Plaintiff failed to provide or timely provide certain data, files, content and support personnel which prevented Defendant from timely performing its contractual obligations.

As and For A Fourth Affirmative Defense

(Comparative Fault)

4. The Complaint is barred in whole or in part because, to the extent that there was a breach of contract, Plaintiff failed to provide or timely provide certain data, files, content and support personnel which prevented Defendant from timely performing contractual obligations.

5. The Complaint is barred in whole or in part because to the extent that there was a breach of contract, Plaintiff breached first by failing to pay Defendant compensation due under additional agreements made between Ingenes and Induction subsequent to the date of the contact.

6. The Complaint is barred in whole or in part because to the extent that there was a breach of contract, Plaintiff breached by failing to conduct a Project evaluation following termination to account for amounts owed to Defendant.

7. The Complaint is barred in whole or in part because Defendant reasonably completed all of its obligations which Plaintiff had not prevented or otherwise interfered with due to Plaintiff's non-compliance.

As and For A Fifth Affirmative Defense

(Bad Faith, Unclear Hands and Other Equitable Remedies)

8. The Complaint is barred in whole or in part under the equitable doctrines of acquiescence, bad faith, equitable estoppel, waiver, and unclean hands.

As and For a Sixth Affirmative Defense

(Accord and Satisfaction)

9. The Complaint is barred in whole or in part with respect to the agreement as there was accord and satisfaction with respect to any claim respecting the same.

As and For a Seventh Affirmative Defense

10. The Complaint is barred in whole or in part in that to the extent that Plaintiffs have suffered damages, if any, such damage was caused by the acts and/or omissions of Plaintiffs and/or their respective directors, officers, agents and/or employees.

COUNTERCLAIMS

Defendant/Counter-Plaintiff Ingenes, LLC by and through its undersigned counsel, as and for its Counterclaims against Plaintiff/Counter-Defendant Induction Therapies, LLC (“Plaintiff” or “IT”), alleges as follows:

1. This counterclaim involves a claim for breach of contract relating to certain services performed that were authorized by IT and performed by Ingenes on the behalf of IT relating to the FDA approval submission for a medical device.

2. In summary, Induction breached and otherwise failed in its contractual obligations by failing to pay Ingenes for the services performed and costs it incurred.

PARTIES

3. Defendant/Counter-Plaintiff Ingenes is a Maryland limited liability corporation having an address at 10135 Treble Court, Rockville, MD 20850.

4. Plaintiff/Counter-Defendant Induction Therapies (“IT”) on information and belief a South Dakota limited liability company and has a principal place of business in Kentucky (“IT”).

JURISDICTION

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, since there is complete diversity of citizenship between the parties and the amount in controversy exceeds \$75,000, exclusive of costs.

6. This Court also has ancillary, pendant and supplementary jurisdiction over Ingenes breach of contract claims and over Induction Therapies, LLC.

FACTS COMMON TO ALL COUNTS

7. IT and Ingenes entered into a consulting agreement on or about December 31, 2018 (the “December Agreement”) for services relating to the submission to the FDA of an 510(k) submission seeking approval of a medical device (the “IT Device”).

9. IT did not provide the required information including a risk management file, user manuals, bill of materials, sample photos, electrical/electronic drawings as outlined in the December Agreement and did not provide the necessary supporting documentations in a timely manner as requested by the testing laboratory to successfully complete the testing of the IT Device.

10. Ingenes was not able to obtain sufficient information from IT and its Chinese contract manufacturer who was not willing to share information about the IT Device or its manufacturing process.

11. The failure of the Chinese manufacture to provide information about the IT Device changed the scope of work under the December Agreement.

12. The parties agreed that Ingenes would perform additional services on behalf of IT outside the scope of those contemplated under the December Agreement also relating to seeking FDA approval of the IT Device and that Ingenes would be compensated for these additional services.

13. IT requested that Ingenes travel to its contract manufacturing facility in China to collect the materials and information for a risk management file and quality management system file (Additional Services) for the IT Device.

14. IT agreed to pay to Ingenes for the Additional Services and costs, including traveling expenses, for time spent to gather the required materials and information in China.

15. Ingenes performed these Additional Services, including travel to China and the collection of materials and Ingenes invoiced IT for the services and costs.

16. IT failed to pay Ingenes for the Additional Services.

17. After the testing work on the device had been initiated, it was determined that some of the critical components used in the IT Device were not quality tested or certified.

18. The failure to perform quality testing on the IT Device led to failure during laboratory testing which further changed the scope of work.

19. Ingenes performed or arranged for additional testing which involved additional costs and time, not provided for under the December Agreement and IT agreed to pay for such additional testing services and related consulting.

20. Ingenes invoiced IT for the additional testing services and related costs.

21. IT failed to pay Ingenes for the additional testing and consulting services.

22. At the time December Agreement was signed, the parties had not located an animal testing facility for non-clinical performance testing. Per the December Agreement, IT requested that Ingenes find a GLP Certified animal testing facility/laboratory to test the performance of the IT Device. IT agreed to the testing plan and associated cost to complete the animal testing work.

23. However, IT further requested that Ingenes personnel travel to Spain to assist with the planning and execution of the study to successfully complete the non-clinical performance testing of the device, services that were not included in the December Agreement.

24. The travel and related consulting fees associated with work in Spain (“Spanish Work”) further changed the scope of work as provided for under the December Agreement.

25. Ingenes provided an estimate of the travel expenses and consulting fee for the time for the Spanish Work and Induction agreed to pay Ingenes travel expenses and consulting fees.

26. Ingenes invoiced IT for the Spanish Work and related costs.

27. IT failed to pay Ingenes the travel expenses or the consulting fees as agreed for the Spanish Work.

28. Upon completion of the animal testing work, IT was not satisfied with the test report and sought modifications of the completed animal model performance test report for the FDA 510(k) submission. Since the animal testing lab is a GLP Certified Lab, there were limitation as to what modifications can be made to testing reports. IT requested modification to the test reports delayed in finalizing the test report and increased the time and cost of the project.

29. Since IT did not have all the required test report to submit a complete 510(k) submission to FDA, Ingenes advised IT to first complete the test reports before filing the 510(k) submission.

30. Notwithstanding the known deficiencies in the submission, IT requested that Ingenes arrange to file the incomplete 510(k) submission.

31. Ingenes filed the 510(k) Submission on December 31, 2019.

32. Throughout the period of work and since December 2019 , Ingenes continuously discussed with IT the expanded scope of additional work and time required and advised of the

additional costs that would be required to complete the work. IT approved the additional work by email or verbal confirmation.

33. Ingenes recommended waiting until all of the information had been assembled to file a complete the 510(k) submission to FDA, but IT refused to pay for any additional testing cost, documentation and related consulting fees, travel related expenses and fees relating to the review of draft test reports. IT also failed to pay Ingenes its second instalment payment for remaining work performed in connection with the 510(k) submission.

COUNT I

(Breach of Contract)

34. Ingenes repeats and realleges the foregoing Paragraphs 1 to 31 of these Counterclaims, as if fully set forth herein.

35. Ingenes has performed the agreed upon services in incurred costs that IT agreed to pay for and reimburse.

36. Ingenes has made demands for payment and IT has refused to pay the amounts owed in the amount of \$ 124,873.34.

37. IT has materially breached its agreement with Ingenes, *inter alia*, by failing to render the amount due.

39. Ingenes has been damaged by the breach and IT should be ordered to pay \$ 124,873.34. the amount IT owes Ingenes..

COUNT III

(Unjust Enrichment)

36. Ingenes repeats and realleges the foregoing Paragraphs 1 to 35 of these Counterclaims, as if fully set forth herein.

37. In the alternative, IT has been unjustly enriched by the services Ingenes rendered and costs incurred for IT which it was not paid.

38. Ingenes has provided benefits to IT as recited above, and IT has not paid Ingenes for its services or for the costs it incurred on IT's behalf.

39. Wherefore IT should be ordered to pay an amount to Ingenes to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Ingenes respectfully prays for the following relief:

(a) Awarding damages to Ingenes and the costs it incurred on behalf of IT in an amount of \$124,873.34;

(b) Awarding Ingenes its attorney's fees and expenses incurred in connection with Induction's Complaint and Ingenes' Counterclaims;

(c) Awarding Ingenes prejudgment interest;

(d) Awarding other relief to Ingenes as just and proper.

Dated: July 14, 2021

Respectfully submitted,

/s/Andrew C. Aitken
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